

FOR UTILITY/DESIGN
CIP/PCT NATIONAL/PLANT
ORIGINAL/SUBSTITUTE/SUPPLEMENTAL
DECLARATIONS

JUN 27 2002

DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICEPW
FORM

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the INVENTION ENTITLED METHODS AND DEVICES FOR QUANTITATION OF GLYCATED PROTEIN

the specification of which (CHECK applicable BOX(ES))

X
BOX(ES) → A. ☐ is attached hereto.
→ B. ☒ was filed on January 31, 2002 as U.S. Application No. 10/061,438
→ C. ☐ was filed as PCT International Application No. PCT/ / On
and (if applicable to U.S. or PCT application) was amended on

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. 1.56. Except as noted below, I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT International Application which designated at least one other country than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT International Application, filed by me or my assignee disclosing the subject matter claimed in this application and having a filing date (1) before that of the application on which priority is claimed, or (2) if no priority claimed, before the filing date of this application:

| PRIOR FOREIGN APPLICATION(S) Number | Country | Day/MONTH/Year Filed | Date first Laid- open or Published | Date Patented or Granted | Priority NOT Claimed |
|--|---------|----------------------|---------------------------------------|-----------------------------|----------------------|
|--|---------|----------------------|---------------------------------------|-----------------------------|----------------------|

Except as noted below, I hereby claim domestic priority benefit under 35 U.S.C. 119(e) or 120 and/or 365(c) of the indicated United States applications listed below and PCT international applications listed above or below and, if this is a continuation-in-part (CIP) application, insofar as the subject matter disclosed and claimed in this application is in addition to that disclosed in such prior applications, I acknowledge the duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of each such prior application and the national or PCT international filing date of this application:

| PRIOR U.S. PROVISIONAL, NONPROVISIONAL AND/OR PCT APPLICATION(S) Application No. (series code/serial no.) | Day/MONTH/Year Filed | Status pending, abandoned, patented | Priority NOT Claimed |
|--|----------------------|--|----------------------|
| 60/265,229 | 31 January 2001 | Pending | |
| 10/062,281 | 30 January 2002 | Pending | |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Please direct all correspondence to Suzanne L. Biggs, Pillsbury Winthrop LLP, 11682 El Camino Real, Suite 200, San Diego, CA, 92130 and direct all telephone calls to (858) 509-4095

And I hereby appoint the below-named persons individually and collectively as my attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and with the resulting patent, and I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct the above Firm and/or a below attorney in writing to the contrary.

| | | | | | | | |
|--------------------|-------|-------------------|-------|-----------------------|-------|------------------------|--------|
| G. Lloyd Knight | 17698 | Glenn J. Perry | 28458 | Stephen C. Glazier | 31361 | William P. Atkins | 38821 |
| Kevin E. Joyce | 20508 | Kendrew H. Colton | 30368 | Richard H. Zaitlen | 27248 | Paul L. Sharer | 36004 |
| George M. Sirilla | 18221 | G. Paul Edgell | 24238 | Roger R. Wise | 31204 | Anthony L. Miele | 34393 |
| Dale S. Lazar | 28872 | Lynn E. Eccleston | 35861 | Michael R. Dzwonczyk | 36787 | Russ Weinzimmer | 36717 |
| Paul E. White, Jr. | 32011 | Timothy J. Klima | 34852 | W. Patrick Bengtsson | 32456 | Arthur J. O'Dea | 42,952 |
| Suzanne L. Biggs | 30158 | David A. Jakopin | 32995 | Jack S. Barufka | 37087 | Jonathan E. Jobe, Jr. | 28429 |
| | | Mark G. Paulson | 30793 | Adam R. Hess | 41835 | John R. Wetherell, Jr. | 31678 |
| | | James Y.C. Sze | 43943 | Victor J. Castellucci | 43535 | Robert M. Bedgood | 43488 |

(1) INVENTOR'S SIGNATURE:

Date: 6/6/02

| | | |
|---------------------|-------------------------|--------------------------|
| Ralph | P. | McCROSKEY |
| First | Middle Initial | Family Name |
| Residence | San Diego | California/United States |
| City | State/Foreign Country | Country of Citizenship |
| Post Office Address | 7464 Mason Heights Lane | |
| (include Zip Code) | 92126 | |

(2) INVENTOR'S SIGNATURE:

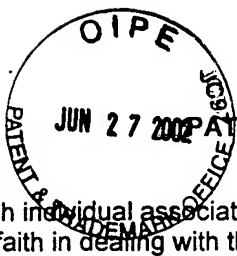
Date:

| | | |
|---------------------|-----------------------|--------------------------|
| Cameron | E. | MELTON |
| First | Middle Initial | Family Name |
| Residence | Nine Mile Falls | Washington/United States |
| City | State/Foreign Country | Country of Citizenship |
| Post Office Address | 6219 Moriah | |
| (include Zip Code) | 99026 | |

FOR ADDITIONAL INVENTORS, "X" box ☐ and proceed on the attached page to list each additional inventor.

Atty. Dkt. No. 070788-0282091

(C/M#)



COPY OF PAPERS
ORIGINALLY FILED

Rule 56(a) & (b) = 37 C.F.R. 1.56(a) & (b)

PATENT AND TRADEMARK CASES - RULES OF PRACTICE
DUTY OF DISCLOSURE

- (a) ...Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [Patent and Trademark] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability... (b) information is material to patentability when it is not cumulative and (1) It also establishes by itself, or in combination with other information, a prima facie case of unpatentability of a claim or (2) refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability

PATENT LAWS 35 U.S.C.

§102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless--

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months* before the filing of the application in the United States, or
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or
- (f) he did not himself invent the subject matter sought to be patented, or
- (g) Before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

§103. Condition for patentability; non-obvious subject matter

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made. . . .
- (c) Subject matter developed by another person, which qualified as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

* Six months for Design Applications (35 U.S.C. 172).

#3

FOR UTILITY/DESIGN
CIP/PCT NATIONAL/PLANT
ORIGINAL/SUBSTITUTE/SUPPLEMENTAL
DECLARATIONSRULE 63 (37 C.F.R. 1.63)
DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICEPW
FORM

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the INVENTION ENTITLED METHODS AND DEVICES FOR QUANTITATION OF GLYCATED PROTEIN

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PRIOR FOREIGN APPLICATION(S)

| Number | Country | Day/MONTH/Year Filed | Date first Laid-open or Published | Date Patented or Granted | Priority NOT Claimed |
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| Application No. (series code/serial no.) | Day/MONTH/Year Filed | Status | Priority NOT Claimed |
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| 60/265,229 | 31 January 2001 | pending, abandoned, patented | |
| 10/062,281 | 30 January 2002 | Pending | |
| | | Pending | |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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And I hereby appoint the below-named persons individually and collectively as my attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and with the resulting patent, and I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct the above Firm and/or a below attorney in writing to the contrary.

| | | | | | | | |
|--------------------|-------|-------------------|-------|-----------------------|-------|------------------------|--------|
| G. Lloyd Knight | 17698 | Glenn J. Perry | 28458 | Stephen C. Glazier | 31361 | William P. Atkins | 38821 |
| Kevin E. Joyce | 20508 | Kendrew H. Colton | 30368 | Richard H. Zaitlen | 27248 | Paul L. Sharer | 36004 |
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| Suzanne L. Biggs | 30158 | David A. Jakopin | 32995 | Jack S. Baruffa | 37087 | Jonathan E. Jobe, Jr. | 28429 |
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| | | James Y.C. Sze | 43943 | Victor J. Castellucci | 43535 | Robert M. Bedgood | 43488 |

(1) INVENTOR'S SIGNATURE:

Date:

| | | |
|---------------------|-------------------------|--------------------------|
| Ralph | P. | McCROSKEY |
| First | Middle Initial | Family Name |
| Residence | San Diego | California/United States |
| City | State/Foreign Country | Country of Citizenship |
| Post Office Address | 7464 Mason Heights Lane | |
| (include Zip Code) | 92126 | |

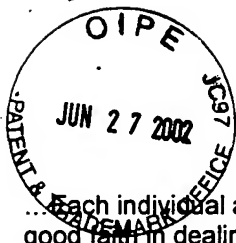
(2) INVENTOR'S SIGNATURE:

Date:

| | | |
|---------------------|-----------------------|--------------------------|
| Cameron | E. | MELTON |
| First | Middle Initial | Family Name |
| Residence | Nine Mile Falls | Washington/United States |
| City | State/Foreign Country | Country of Citizenship |
| Post Office Address | 6219 Moriah | |
| (include Zip Code) | 99026 | |

FOR ADDITIONAL INVENTORS, "X" box ☐ and proceed on the attached page to list each additional inventor.Atty. Dkt. No. 070788-0282091

(C/M#)



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COPY OF PAPERS
ORIGINALLY FILED

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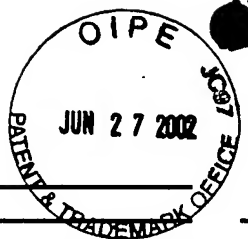
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- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months* before the filing of the application in the United States, or
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or
- (f) he did not himself invent the subject matter sought to be patented, or
- (g) Before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

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- (c) Subject matter developed by another person, which qualified as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

* Six months for Design Applications (35 U.S.C. 172).



#5
COPY OF PAPERS
ORIGINALLY FILED

Inventor(s): Ralph P. McCroskey, et al.

Appln. No.: 10/061,438

or Patent No.: _____

Filed: January 31, 2002

or Issued.: _____

(Atty. Dkt.

070788-0282091/

M# / Client Ref.

Title: METHODS AND DEVICES FOR QUANTITATION OF GLYCATED PROTEIN

SMALL ENTITY STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(d) and 1.27 (c)) - **SMALL BUSINESS CONCERN**

I hereby state that I am



the owner of the small business concern identified below:



an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN Scripps Laboratory

ADDRESS OF CONCERN 6838 Flanders Drive, San Diego, California 92121

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled: METHODS AND DEVICES FOR QUANTITATION OF GLYCATED PROTEIN

by inventor(s) Ralph P. McCroskey and Cameron E. Melton described in

x →



the specification filed herewith,

ne →



Application No. 10/061,438, filed January 31, 2002

box →



Patent No. _____, issued

If the rights held by the above identified small business concern are not exclusive, each small entity individual, concern or organization having rights to the invention is listed in (A) and (B) below and no rights to the invention are held by any person, other than the inventor, who could not qualify under 37 CFR 1.9(c) as an independent inventor if that person had made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

(A) FULL NAME of assignee/licensee/grantee/conveyee*

ADDRESS

☐ INDIVIDUAL

☐ SMALL BUSINESS CONCERN

☐ NONPROFIT ORGANIZATION

(B) FULL NAME of assignee/licensee/grantee/conveyee*

ADDRESS

☐ INDIVIDUAL

☐ SMALL BUSINESS CONCERN

☐ NONPROFIT ORGANIZATION

*NOTE:

Separate statement is required from each person, concern or organization named in (A) and (B) above having rights to the invention, averring to his/her/its status as a small entity. (37 CFR 1.27)

I acknowledge the duty to file, in this case, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Simon Khoury

TITLE OF PERSON OTHER THAN OWNER

ADDRESS OF PERSON SIGNING 6838 Flanders Drive, San Diego, CA 92121

SIGNATURE

DATE

6/6/02